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Docket No. CEN0250

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : George Heavner, et a.
Serial No. : 09/920,137 Art Unit:
Filed : August 1, 2001 Examiner:
For : ANTI-TNF ANTIBODIES, COMPOSITIONS, METHODS AND USES

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(Date of Deposit)

Guy Kevin Townsend

(Name of applicant, assignee, or Registered Representative)

(Signature)

June 11, 2002

(Date of Signature)

Commissioner for Patents
Washington, D.C. 20231

INFORMATION DISCLOSURE STATEMENT

Dear Sir:

Pursuant to 37 C.F.R. §1.56 and in accordance with 37 C.F.R. §§1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 C.F.R. §1.56(b).

Applicant(s) reserve(s) the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist.

☒ In accordance with §1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified national application (other than a continued prosecution application under §1.53(d)), within three months of the date of entry



into the national stage of the above identified application as set forth in §1.491, or before the mailing date of a first Office Action on the merits of the above-identified application, or before the mailing date of a first Office Action after the filing of a request for continued examination under §1.114, no additional fee is required.

☐ In accordance with §1.129(a), this Information Disclosure Statement is being filed in connection with ☐ the first or ☐ second After Final Submission, therefore:

☐ Statement in Accordance with §1.97(e) (attached); or

☐ Please charge Deposit Account No. 10-0750/ / the fee of \$180.00 as set forth in §1.17(p).

☐ In accordance with §1.97(c), this Information Disclosure Statement is being filed after the period set forth in §1.97(b) above but before the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311, or an action that otherwise closes prosecution and that it is accompanied by one of:

☐ Statement in Accordance with §1.97(e) (attached); or

☐ Please charge Deposit Account No. 10-0750/ / the fee of \$180.00 as set forth in §1.17(p).

☐ In accordance with §1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311 but before the payment of the Issue Fee. Applicant(s) hereby petition(s) for consideration of this Information Disclosure Statement. Included are: Statement in Accordance with §1.97(e) as set forth below and the fee of \$180.00 as set forth in §1.17(p).


☒ Copies of each of the references listed on the attached Form PTO-1449 are enclosed herewith.

☐ Copies of references listed on the attached Form PTO-1449 are enclosed herewith EXCEPT THAT:

- ☐ In view of the voluminous nature of references [list as appropriate], and the likelihood that these references are available to the Examiner, copies are not enclosed herewith.
- ☐ If any of the foregoing publications are not available to the Examiner, Applicant will endeavor to supply copies at the Examiner's request.
- ☒ There are no listed references which are not in the English language.
- ☐ The relevance of those listed references which are not in the English language is as follows:
- ☐ Attached are copies of search report(s) from corresponding patent application(s), which are listed on the attached Submission Under MPEP 609 D.
- ☐ Attached are the following non-published pending patent applications which may be deemed relevant, which are listed on the attached Submission Under MPEP 609 D.

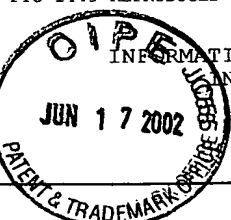
Please charge any deficiency or credit any overpayment to Deposit Account No. 10-0750/CEN0250/GKT. This form is submitted in triplicate.

Respectfully submitted,


Guy Kevin Townsend
Reg. No. 34,033
Attorney for Applicants

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(732) 524-2517

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GROUP

U. S. PATENT DOCUMENTS

EXAM- INER INI- TIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE IF APPROPRIATE	
	AA	4,603,106	07/29/86	Cerami et al.	435	7		
	AB	4,822,776	04/18/89	Cerami et al.	514	21		
	AC	5,231,024	7/27/93	Moeller et al.	435	240.27		
	AD	5,342,613	08/30/94	Creaven et al.	424	85.1		
	AE	5,658,570	08/19/97	Newman et al.	424	184.1		
	AF	5,656,272	12/12/97	Le, et al.	424	133.1		
	AG	5,698,195	12/16/97	Le, et al.	424	133.1		
	AH	5,750,105	5/12/98	Newman et al.	424	133.1		
	AI	5,888,511	03/30/99	Skurkovich et al.	424	145.1		
	AJ	5,919,452	07/06/99	Le, et al.	424	133.1		
	AK	5,958,413	09/28/99	Anagnostopulos et al.	424	178.1		
	AA2	5,993,833	11/30/99	DeLacharriere et al.	424	401		
	AB2	6,190,691 B1	02/20/01	Mak	424	449		
	AC2	6,277,969B1	08/21/01	Le, et al.	536	23.1		
	AD2	6,284,471B1	09/04/01	Le, et al.	435	7.1		

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION YES NO	
	AL	0212489B1	03/04/87	EPO				
	AM	0218868	04/22/87	EPO				
	AN	0260610B1	03/23/88	EPO				
	AO	0288088B1	10/26/88	EPO				

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AP	0308378B1	22 MAR 89	EPO				
AQ	0350690A2	17 JAN 90	EPO				
AL2	0351789B1	24 JAN 90	EPO				
AM2	WO90/00902	08 FEB 90	PCT				
AN2	0380068A1	01 AUG 90	EPO				
AO2	0393438A2	24 OCT 90	EPO				
AP2	0398327B1	22 NOV 90	EPO				
AQ2	0412486B1	13 FEB 91	EPO				
AL3	WO91/02078	21 FEB 91	PCT				
AM3	0486526B2	07 MAR 91	EPO				
AN3	0433900A1	26 JUN 91	EPO				
AO3	WO91/09967	11 JUL 91	PCT				
AP3	WO92/16553	19 MAR 92	PCT				
AQ3	WO92/07076	30 APR 92	PCT				
AL4	0 526 905 A3	07 AUG 92	EPO				
AM4	WO92/11383	09 JUL 92	PCT				
AN4	WO92/13095	06 AUG 92	PCT				
AO4	WO93/02108	04 FEB 93	PCT				
AP4	0526905A3	10 FEB 93	EPO				
AQ4	AU-B-17649/92	23 MAY 96	AU				
AL5	EP 0 610 210 B1	16 MAY 01	EPO				

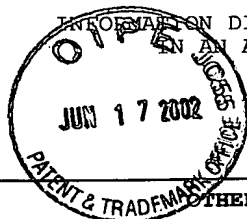
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GROUP



OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

AR	Beutler, B. et al., "Identity of tumour necrosis factor and the macrophage-secreted factor cachectin," <i>Nature</i> , 316:552-554 (1985).
AS	Beutler, B. et al., "Passive Immunization Against Cachectin/Tumor Necrosis Factor Protects Mice from Lethal Effect of Endotoxin," <i>Science</i> , 229:869-871 (1985).
AT	Morrison, Sherie L., "Transfectomas Provide Novel Chimeric Antibodies," <i>Science</i> , 229:1202-1207 (1985).
AU	Aggarwal, Bharat B. et al., "Human Tumor Necrosis Factor Production, Purification and Characterization," <i>J. of Biol. Chem.</i> , 260(4):2345-2354 (1985).
AV	Beutler, B. et al., "Purification of Cachectin, A Lipoprotein Lipase-Suppressing Hormone Secreted by Endotoxin-induced RAW 264.7 Cells," <i>J. Exp. Med.</i> , 161:984-995 (1985).
AW	Paulus, H., APreparation and Biomedical Applications of Bispecific Antibodies@, <i>Behring Inst. Mitt</i> , No.78:118-132 (1985).
AX	Hayashi, H. et al., "An Enzyme-linked Immunosorbent Assay for Recombinant Human Tumor Necrosis Factor Using Monoclonal Antibody," <i>Recent Adv. Chemother</i> , 820-821 (1985).
AY	Liang, Chi-Ming et al., "Production and Characterization of Monoclonal Antibodies Against Recombinant Human Tumor Necrosis Factor/Cachectin," <i>Biochem. & Biophys. Res. Comm.</i> , 137(2):847-854 (1986).
AZ	Hirai, Makoto et al., "Production and characterization of monoclonal antibodies to human tumor necrosis factor," <i>J. of Immun. Methods</i> , 96:57-62 (1987).
AR2	Piguet, Pierre-Francois et al., "Tumor Necrosis Factor/Cachectin is an Effector of Skin and Gut Lesions of the Acute Phase of Graft-vs.-Host Disease," <i>J. Exp. Med.</i> , 166:1280-1289 (1987).
AS2	Meager, Anthony et al., "Preparation and Characterization of Monoclonal Antibodies Directed Against Antigenic Determinants of Recombinant Human Tumour Necrosis Factor (rTNF)," <i>Hybridoma</i> , 6(3):305-311 (1987).
AT2	Fendly, Brian M. et al., "Murine Monoclonal Antibodies Defining Neutralizing Epitopes on Tumor Necrosis Factor," <i>Hybridoma</i> , 6(4):359-370 (1987).
AU2	Bringman, Timothy S. and Aggarwal, Bharat B., "Monoclonal Antibodies to Human Tumor Necrosis Factors Alpha and Beta: Applications for Affinity Purification, Immunoassays, and as Structural Probes," <i>Hybridoma</i> , 6(5):489-507 (1987).
AV2	Tracey, Kevin J. et al., "Anti-cachectin/TNF monoclonal antibodies prevent septic shock during lethal bacteraemia," <i>Nature</i> , 330:662-664 (1987).

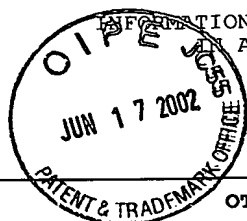
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AW2	Nagai, M. et al., "Antibody to tumor necrosis factor (TNF) reduces endotoxin fever," <i>Experientia</i> , 44:606-607 (1988).
AX2	Shimamoto, Yoshinori et al., "Monoclonal antibodies against human recombinant tumor necrosis factor: prevention of endotoxic shock," <i>Immunology Letters</i> , 17:311-318 (1988).
AY2	Di Giovine, Francesco, S. et al., "Tumour necrosis factor in synovial exudates," <i>Annals of the Rheumatic Diseases</i> , 47:768-772 (1988).
AZ2	Sunahara, N. et al., "Simple enzyme immunoassay methods for recombinant human tumor necrosis factor and its antibodies using a bacterial cell wall carrier," <i>J Immunol Methods</i> , 109:203-214 (1988).
AR3	Exley, A.R. et al., "Monoclonal Antibody (Mab) to Recombinant Human Tumour Necrosis Factor (rhTNF) in the Prophylaxis and Treatment of Endotoxic Shock in Cynomolgus Monkeys," <i>Medical Research Society</i> , Abstract 184, p. 50 (1989).
AS3	Cross, A.S. et al., "Pretreatment with Recombinant Murine Tumor Necrosis Factor α Cachectin and Murine Interleukin 1 α Protects Mice from Lethal Bacterial Infection," <i>J of Exp Med.</i> , 169:2021-2027 (1989).
AT3	Whittle, Nigel, et al., "Construction and Expression of a CDR-Grafted Anti-TNF Antibody," <i>J. Cell Biochem</i> , Supl. 13A:96 (1989).
AU3	Duncombe, Andrew S. et al., "Tumor Necrosis Factor Mediates Autocrine Growth Inhibition in a Chronic Leukemia," <i>J Immunol</i> , 143:3828-3834 (1989).
AV3	Aderka, Dan et al., "IL-6 Inhibits Lipopolysaccharide-Induced tumor Necrosis Factor Production in Cultured Human Monocytes, U937 Cells, and in Mice," <i>J Immunol</i> , 143:3517-3523 (1989).
AW3	Eck, Michael J. and Sprang, Stephen R., "The Structure of Tumor Necrosis Factor- at 2.6 \square Resolution," <i>J Biol Chem</i> , 264:17595-17605 (1989).
AX3	Gillies, Stephen D. et al., "High-level expression of chimeric antibodies using adapted cDNA variable region cassettes," <i>J Immunol Methods</i> , 125:191-202 (1989).
AY3	Engelmann, Hartmut et al., "A Tumor Necrosis Factor-binding Protein Purified to Homogeneity from Human Urine Protects Cells from Tumor Necrosis Factor Toxicity," <i>J. of Bio. Chem.</i> , 264(20):11974-11980 (1989).
AZ3	Kawasaki, Hajime et al., "Analysis of Endotoxin Fever in Rabbits by Using a Monoclonal Antibody to Tumor Necrosis Factor (Cachectin)," <i>Infection and Immunity</i> , 57(10):3131-3135 (1989).

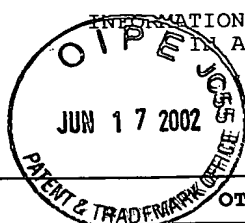
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AR4	Fong, Yuman et al., "Antibodies to Cachectin/Tumor Necrosis Factor Reduce Interleukin 1 β and Interleukin 6 Appearance During Lethal Bacteremia," <i>J. Exp. Med.</i> , 170:1627-1633 (1989).
AS4	Collins, M.S. et al., "Immunoprophylaxis of Polymicrobial Cellulitis with a Human Monoclonal Antibody Against Lipopolysaccharide Antigen of <i>Pseudomonas aeruginosa</i> ," Abstract E-63, <i>Abstracts of Annual Meeting 1989</i> .
AT4	Kameyama, Koh-zoh, et al., "Convenient plasmid vectors for construction of chimeric mouse/human antibodies," <i>FEBS Lett</i> , 244:301-306 (1989).
AU4	Genebank Accession, No. N90300 (1989, November 1).
AV4	Engelmann, Hartmut et al., "Two Tumor Necrosis Factor-binding Proteins Purified from Human Urine," <i>J. of Bio. Chem.</i> , 265(3):1531-1536 (1990).
AW4	Tavernier, Jan et al., "Analysis of the Structure-Function Relationship of Tumour Necrosis Factor. Human/Mouse Chimeric TNF Proteins: General Properties and Epitope Analysis," <i>J. Mol. Biol.</i> , 211:493-501 (1990).
AX4	Lucas, R. et al., "Generation and characterization of a neutralizing rat anti-rm TNF- α monoclonal antibody," <i>Immunology</i> , 71:218-223 (1990).
AY4	Hinshaw, L.B. et al., "Survival of Primates in LD ₁₀₀ Septic Shock Following Therapy with Antibody to Tumor Necrosis Factor (TNF α)," <i>Circulatory Shock</i> , 30:279-292 (1990).
AZ4	Nophar, Yaron et al., "Soluble forms of tumor necrosis factor receptors (TNF-Rs). The cDNA for the type 1 TNF-R, cloned using amino acid sequence data of its soluble form, encodes both the cell surface and a soluble form of the receptor," <i>The EMBO Journal</i> , 9(10):3269-3278 (1990).
AR5	Verhoef, J. and Torensma, R., "Prospects for Monoclonal Antibodies in the Diagnosis and Treatment of Bacterial Infections," <i>Eur. J. Clin. Microbiol. Dis.</i> , 9(4):247-250 (1990).
AS5	Loetscher, Hansruedi et al., "Molecular Cloning and Expression of the Human 55 kd Tumor Necrosis Factor Receptor," <i>Cell</i> , 61:351-359 (1990).
AT5	Schall, Thomas J. et al., "Molecular Cloning and Expression of a Receptor for Human Tumor Necrosis Factor," <i>Cell</i> , 61:361-370 (1990).
AU5	Akama, Hideto et al., "Mononuclear Cells Enhance Prostaglandin E ₂ Production of Polymorphonuclear Leukocytes via Tumor Necrosis Factor α ," <i>Biochemical and Biophysical Research Comm.</i> , 168(2):857-862 (1990).
AV5	Exley, A.R. et al., "Monoclonal antibody to TNF in severe septic shock," <i>The Lancet</i> , 335:1275-1277 (1990).

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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)			
	AW5	Möller, Achim et al., "Monoclonal Antibodies to Human Tumor Necrosis Factor α : In Vitro and In Vivo Application," <i>Cytokine</i> , 2(3):162-169 (1990).	
	AX5	Gorman, S.D. and Clark, M.R., "Humanisation of monoclonal antibodies for therapy," <i>Sem Immunol</i> , 2:457-466 (1990).	
	AY5	Echtenacher, Bernd et al., "Requirement of Endogenous Tumor Necrosis Factor/Cachectin for Recovery from Experimental Peritonitis," <i>J. of Immunology</i> , 145(11):3762-3766 (1990).	
	AZ5	Ruddle, Nancy H. et al., "An Antibody to Lymphotoxin and Tumor Necrosis Factor Prevents Transfer of Experimental Allergic Encephalomyelitis," <i>J. Exp. Med.</i> , 172:1193-1200 (1990).	
	AR6	Von Asmuth, E.J.U. et al., "Tumour Necrosis Factor Alpha (TNF- α) and Interleukin 6 in a Zymosan-Induced Shock Model," <i>Scand. J. Immunol.</i> , 32:313-319 (1990).	
	AS6	Herve, P. et al., "Monoclonal Anti TNF α Antibody for the Treatment of Severe Acute GvHD in Humans," Abstract 3.25, <i>Lymphoma Res.</i> 9:591 (1990).	
	AT6	Silva, Ayona T. et al., "Prophylactic and Therapeutic Effects of a Monoclonal Antibody to Tumor Necrosis Factor- α in Experimental Gram-Negative Shock," <i>J. of Infectious Diseases</i> , 162:421-427 (1990).	
	AU6	Opal, Steven M. et al., "Efficacy of a Monoclonal Antibody Directed Against Tumor Necrosis Factor in Protecting Neutropenic Rats from Lethal Infection with <i>Pseudomonas aeruginosa</i> ," <i>J. of Infectious Diseases</i> , 161:1148-1152 (1990).	
	AV6	Fong, Yuman and Lowry, Stephen F., "Tumor Necrosis Factor in the Pathophysiology of Infection and Sepsis," <i>Clin Immunol Immunopathol</i> , 55:157-170 (1990).	
	AW6	Starnes, H. Fletcher, Jr., et al., "ANTI-IL-6 Monoclonal Antibodies Protect Against Lethal <i>Escherichia Coli</i> Infection and Lethal Tumor Necrosis Factor. Challenge in Mice," <i>J Immunol</i> , 145:4185-4191 (1990).	
	AX6	Genebank Accession, No. M32046 (1990, June 15).	
	AY6	Smith, Craig R., "Human and Chimeric Antibodies to LPS and TNF," 4Abstract, <i>Endotoxemia & Sepsis Conference</i> (1991).	
	AZ6	Bodmer, Mark, "Humanized Antibodies for Anti-TNF Therapy," Abstract, <i>Endotoxemia & Sepsis Conference</i> (1991).	
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AR7 Aderka, Dan, "Role of Tumor Necrosis Factor in the Pathogenesis of Intravascular Coagulopathy of Sepsis: Potential New Therapeutic Implications," *Isr J Med Sci*, 27:52-60 (1991).

AS7	Galloway, Cynthia J. et al., "Monoclonal anti-tumor necrosis factor (TNF) antibodies protect mouse and human cells from TNF cytotoxicity," <i>J. of Immunological Methods</i> , 140:37-43 (1991).
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AT7	Waldmann, Thomas A., "Monoclonal Antibodies in Diagnosis and Therapy," <i>Science</i> , 252:1657-1662 (1991).
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AU7	Lassalle, Ph., et al., "Potential Implication of Endothelial Cells in Bronchial Asthma," <i>Int Arch Allergy Appl Immunol</i> , 94:233-238 (1991).
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AV7	Aderka, Dan et al., "The Possible Role of Tumor Necrosis Factor (TNF) and Its Natural Inhibitors, The Soluble-TNF Receptors, In Autoimmune Diseases," <i>Israel J. Med. Sci.</i> , 28(2):126-130 (1992).
-----	--

AW7	Pennington, James, "TNF: Therapeutic Target in Patients with Sepsis," <i>ASM News</i> , 58(9):479-482 (1992).
-----	---

AX7	Harris, William J. and Emery, Steven, "Therapeutic antibodies - the coming of age," <i>TBTECH</i> , 11:42-44 (1993).
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AY7	Parrillo, Joseph E., "Pathogenetic Mechanisms of Septic Shock," <i>N.E. Journal of Medicine</i> , 328(20):1471-1477 (1993).
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